

DEPARTMENT OF FOOD AND AGRICULTURE

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing is scheduled for this proposal. A public hearing will be held if any interested person, or his or her duly authorized representative, submits a written request for a public hearing to the Department of Food and Agriculture (Department) no later than 15 days prior to the close of the written comment period.

Subject Matter of Proposed Regulations: Bovine Trichomonosis Control Program

Sections Affected: Sections 820, 820.3, 820.55, 820.6 and 820.7

Specific Purpose of Each Adoption, Amendment, or Repeal

Food and Agricultural Code section 10610 authorizes the Department to adopt regulations to control and eradicate cattle diseases, including bovine trichomonosis, through limitations on movement, diagnostic testing, vaccinations, or other appropriate methods of treatment and control. Sections 9562 and 9570 authorize the State Veterinarian to order the quarantine of diseased animals and restrict movement of infected animals or animal products to minimize the risk of an illness that could kill or seriously damage other animals or humans.

In compliance with sections 9562 and 10610 the Department has in place existing Bovine Trichomonosis Control Program regulations under Article 12 of Chapter 2, Division 2, of Title 3 of the California Code of Regulations.

This proposal amends sections 820 (Definitions), 820.3 (Requirements for Entry of Bulls into California), adds new section 820.55 (Trichomonosis Tests), and amends sections 820.6 (Reporting of Positive Test Results) and 820.7 (Trichomonosis Infected Cattle) of Article 12 (Bovine Trichomonosis Control Program). Specifically, this proposal updates the testing protocols to additionally accept the real time quantitative Polymerase Chain Reaction (qPCR) testing procedure for the detection of bovine trichomonosis. The amendments come at the request of the Department's Cattle Health Advisory Task Force pursuant to section 10610 of the Food and Agricultural Code, made at their meeting held February 10, 2010.

Factual Basis

The Department is responsible for promoting and protecting the agricultural industry of California. Further, the Department seeks to enhance, protect and perpetuate the ability of the agricultural industry to produce food and fiber in a way that benefits the general welfare and economy of California, and to maintain the economic well-being of agriculturally dependent rural communities in California pursuant to Food and Agricultural Code sections 401 and 401.5.

The Department's Animal Health Branch is the State's organized, professional veterinary medical unit that protects livestock populations, consumers, and California's economy from catastrophic animal diseases and other health or agricultural problems. The Branch

addresses diseases and other problems that cannot be successfully controlled on an individual animal or herd basis, but require statewide coordinated resources.

Food and Agricultural Code section 9561, authorizes the Department to prevent or eradicate any contagious, infectious, or transmissible disease which affects domesticated animals within the State. Sections 9562 and 9570 authorize the State Veterinarian to order the quarantine of diseased animals and restrict movement of infected animals or animal products to prevent the spread of illness to humans or other animals. Additionally, Food and Agricultural Code section 10610 authorizes the Department to establish procedures for the control and eradication of bovine trichomonosis.

The Legislature has created within the Department the Cattle Health Advisory Task Force under section 10610. The advisory task force consists of 12 members and assists the Department and the Chief of the Animal Health Branch in the administration of cattle health programs for the control or eradication of bovine diseases, including trichomonosis.

Trichomonosis is a disease of cattle causing abortion and infertility. Considered a venereal disease of cattle, it is transmitted by sexual contact with an infected mate. Prevention is the only satisfactory approach to controlling this disease, as no legally approved treatment has been identified at this time. In order to prevent the introduction of and to control the spread of existing trichomonosis in California's herds, the Department requires specified testing of cattle entering the State, and cattle maintained in herds affected with and exposed to the disease (California Code of Regulations, Title 3, sections 820.8 and 820.7).

At the February 10, 2010 Cattle Health Advisory Task Force meeting held at the University of California, Davis, task force members recommended changes to the existing Bovine Trichomonosis Control Program in an effort to bring California's program up to a level comparable with other states' trichomonosis programs and to encourage greater compliance at controlling trichomonosis within California's cattle industry. Specifically, the task force recommended that the Department additionally accept the real-time quantitative Polymerase Chain Reaction (qPCR) testing procedure, in addition to the existing culture test, used for the detection of trichomonosis. Incorporating the proposed qPCR testing into the existing Trichomonosis Control Program regulations would allow producers and their veterinarians to choose between the existing culture test and the proposed qPCR test when testing for the disease.

From a scientific perspective, and as supported by scientific research, qPCR testing has a greater sensitivity and specificity for detecting the organism *Trichomonas foetus* compared to the existing culture test method. Having greater sensitivity and specificity will result in an overall increase in test accuracy; because PCR technology is DNA based, it can detect trichomonosis infection that has been missed by traditional cultural technology. When trichomonosis testing is conducted using the traditional culturing technique, for example, the handling of samples, transportation, and collection techniques can easily compromise the quality of a trichomonosis test sample (very low organism numbers or dead/dying organisms). Additionally, traditional culturing only identifies the presence of *Trichomonas*, and does not detect dead parasites or differentiate between *Trichomonas foetus* and other species of *Trichomonas*.

For most producers, qPCR testing will save time when moving animals into California or when marketing animals as "trichomonosis free". For example, the existing culture testing protocol requires three (3) consecutive negative trichomonosis tests in order for an animal or herd to be considered "free" of trichomonosis. This means producers must round-up, secure, and individually test each eligible animals three (3) times requiring three (3) separate veterinary appointments and three (3) separate laboratory submissions, at intervals of seven (7) days apart but not more than 28 days apart. With the proposed, optional, qPCR testing, producers will have to round-up, secure, and take samples from the animals only once.

When researching the economics of using the qPCR test, the Department was unable to determine the exact costs; veterinary fees (service call and procedures), personal costs (gathering and securing the animals) and the number of animals tested (number of tests needed) vary from farm to farm and veterinary clinic to veterinary clinic. However, laboratory fees that will be charged to the producer or veterinarian by the testing laboratory should they choose to use the proposed qPCR test are currently estimated at \$25 for each qPCR test conducted.

This proposal amends the regulations to allow producers and veterinarians the choice of using either the proposed qPCR test, or the existing culture test, for the detection of trichomonosis in cattle. The Department is accepting the Cattle Health Advisory Task Force's recommendation to include this optional form of testing for reasons stated above. The justification and rationale for the amendments are outlined below.

1) Amend sections 820 and 820.3 of Article 12, Chapter 2, Division 2, of Title 3 of the California Code of Regulations.

Section 820. Definitions.

Subsection (a)(16) Trichomonosis test. For organizational purposes, the Department proposes to amend the definition of a trichomonosis test by deleting and relocating specific requirements under other section headings. The proposed amended definition of a "trichomonosis test" describes only what a trichomonosis test is. The Department proposes to move specific requirements for conducting trichomonosis testing (recording of the official identification of the animal tested and recording of test results on approved forms) to proposed new section 820.55 Trichomonosis Tests subsections (a) and (d) as described in # 3 below. The Department proposes to amend and relocate the requirement to send test results to the Department within 30 days to section 820.6(d). The Department proposes to delete the statement that all trichomonosis tests are official test as this is no longer accurate.

Section 820.3. Requirements for Entry of Bulls into California.

Subsection (b)(1) amends existing language to include the proposed one (1) negative qPCR test as an option to conducting the three (3) consecutive negative culture tests currently used by producers and veterinarians for trichomonosis testing. This

subsection specifically pertains to bulls entering the State that originate from a herd in which trichomonosis has been diagnosed in the past 24 months.

2) Add new section 820.55 to Article 12, Chapter 2, Division 2, of Title 3 of the California Code of Regulations.

Section 820.55. Trichomonosis Tests.

The Department proposes to add new section 820.55 to specify the requirements of a trichomonosis test.

Subsection (a) originates from the existing definition of a "trichomonosis test" {section 820(a)(16)}, stating that the official identification of the animal tested must be recorded and accompany the sample to the laboratory. This is not a new requirement; however the Department proposes to relocate existing text to this proposed new section for organizational purposes.

Subsection (b) adds new text clarifying the condition in which trichomonosis test samples must arrive at the laboratory. These standards are specified in the trichomonosis handling protocol provided to veterinarians when approved for the sampling and handling of specimens for the diagnosis of trichomonosis as required by existing section 820.5. The trichomonosis handling protocol is also available via the Internet or by contacting the laboratory in writing or by telephone as specified. The Department is including a copy of the trichomonosis handling protocol, as provided by the laboratory, in this rulemaking file, and referenced under "Underlying Data".

This subsection additionally proposes new language to notify veterinarians that negative test results of samples not meeting the handling protocol cannot be used as a regulatory test as specified in the requirements of this article, however, can be used as a herd management tool. Because the handling of samples, transportation, and collection techniques can compromise the quality of the samples, adherence to the handling protocol is critical for an accurate diagnosis of the disease.

Subsection (c) adds new language to specify trichomonosis testing protocols accepted by the Department for detecting trichomonosis. Currently, culture tests are the only accepted tests for trichomonosis in California; however this proposal adds the option for producers and veterinarians to use qPCR testing procedures or the existing culture test. Additionally, the Department is adding, in subsection (c)(3), the acceptance of "other tests" for use as possible trichomonosis testing protocols. Several additional tests for trichomonosis are in the process of becoming possible alternatives for use within the scientific veterinary community, therefore the Department proposes to provide a mechanism to accept these tests when they meet specified criteria as determined and approved by the Department.

Subsection (d) originates from the current definition of a "trichomonosis test" {section 820(a)(16)}, stating that trichomonosis test results must be recorded on forms

approved by the Department for that purpose. This is not a new requirement, however a relocation of existing text to this section for organizational purposes.

3) Amend sections 820.6 and 820.7 of Article 12, Chapter 2, Division 2, of Title 3 of the California Code of Regulations.

Section 820.6. Reporting of Trichomonosis Test Results.

The Department proposes to amend the heading of section 820.6 to clarify the section pertains to the reporting of “all trichomonosis” test results, not just “positive” results as currently stated.

Subsection (d). The requirement to send copies of test results to the Department within 30 days of the test results exists in current section 820(a)(16) “trichomonosis test”. The Department finds this statement is not specific and implies that all tests, whether negative or positive, must be sent to the Department within 30 days, however, existing subsection (b) of 820.6, states that positive test results must be reported to the Department within two (2) days. Therefore, the Department is clarifying that “negative” test results must be sent to the Department with 30 days of the test result, and for organizational purposes, proposes to relocate the requirement to this section.

Section 820.7. Trichomonosis Infected Cattle.

Subsection (a)(2)(A) amends existing language to include the proposed one negative (1) qPCR test as an option to the three (3) consecutive negative tests used by producers and veterinarians for testing herdmate bulls in trichomonosis affected herds.

Subsection (a)(4)(A)3 amends existing language to include the proposed one negative (1) qPCR test as an option to the three (3) consecutive negative tests used by producers and veterinarians for testing herdmate bulls in trichomonosis affected herds entering the State using a Pasture to Pasture Permit.

Subsection (a)(4)(A)4 amends existing language to include the proposed one negative (1) qPCR test as an option to the three (3) consecutive negative tests used by producers and veterinarians for testing herdmate bulls in trichomonosis affected herds that have returned to their state of origin (after entering the State using a Pasture to Pasture Permit) to complete the trichomonosis testing.

Underlying Data

- Minutes from the Cattle Health Advisory Task Force Meeting, February 10, 2010, California Animal Health and Food Safety Laboratory System, University of California, Davis

- California Animal Health and Food Safety Laboratory System, trichomonosis handling protocol, July 9, 2010

Business Impact

The Department has made the initial determination that the proposed regulatory action will not have any significant statewide adverse economic impact directly affecting California businesses including the ability of California businesses to compete with businesses in other states.

This proposal amends existing requirements for the control of bovine trichomonosis by allowing producers and veterinarians the use of an additional test used for the detection of trichomonosis. Because the requirements for California businesses and individuals are based on the voluntary use of qPCR testing, the Department has determined that no adverse impact exists with this proposal. The following compliance requirements are projected to result from the proposed action:

Paperwork: This proposal contains paperwork requirements consisting of laboratory testing for trichomonosis in cattle. Any person conducting trichomonosis testing for the detection of bovine trichomonosis may incur costs. Trichomonosis testing requirements are intended to control and possibly prevent a disease of cattle that will benefit California's cattle industry, promote healthy animals, and make the industry's products marketable both nationally and internationally.

Record Keeping: This proposal does not contain any additional record keeping requirements.

Reporting: This proposal does not contain any additional reporting requirements.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment; however, the livestock industry, veterinary medical practices, or diagnostic laboratories may require specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Department of Food and Agriculture would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.